UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA

IRISH 4 REPRODUCTIVE HEALTH;

NATASHA REIFENBERG;

JANE DOES 1-3;

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

UNITED STATES DEPARTMENT OF LABOR;

UNITED STATES DEPARTMENT OF THE TREASURY;

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services;

EUGENE SCALIA, in his official capacity as Secretary of Labor;

STEVEN MNUCHIN, in his official capacity as Secretary of the Treasury;

and

UNIVERSITY OF NOTRE DAME,

Defendants.

Case No. 3:18-CV-491-PPS-JEM

SECOND AMENDED COMPLAINT

INTRODUCTION

1. This case is a challenge to actions by the United States Departments of Health and Human Services, Labor, and the Treasury (the "Departments"), and the University of Notre Dame that will harm at least tens of thousands of people nationwide, including at Notre Dame. As a result of Defendants' conduct, the four individual Plaintiffs and members of Plaintiff Irish 4 Reproductive Health—along with countless others—are being deprived of the comprehensive

contraceptive coverage to which they are entitled by law, and are being forced to subordinate their own beliefs, health, and equality to the religious beliefs of their university or employer in violation of the Administrative Procedure Act, the Patient Protection and Affordable Care Act of 2010, and the First Amendment to the U.S. Constitution.

2. The ACA requires group health plans and health-insurance issuers to cover, without cost-sharing, a range of preventive health services. Recognizing that women historically have been required to pay more money out-of-pocket for health care, including for contraception and related services, Congress expressly required the inclusion of women's preventive services among the benefits that health plans must cover without copays or other cost-sharing.[1] Since 2011, the Departments' controlling regulations have clarified that these services must include contraception for women and related patient education and counseling, without cost-sharing.

3. Since 2011, the Departments' regulations have contained an exemption from the contraceptive coverage requirement for houses of worship. Since 2013, the regulations have also contained an "accommodation" for certain employers and universities that have religious objections to contraceptive coverage and meet certain criteria. Through the accommodation process, an objecting employer or university may inform the government, or the entity's insurer or third-party administrator, that it has religious objections to providing coverage for contraceptive services. The entity's insurance issuer then fulfills its legal obligation by separately providing payments for contraceptive services. The long-standing regulations thus ensured that women covered by health plans at objecting employers or universities obtain the full range of U.S. Food

[1] This Complaint uses the term "women" because the individual Plaintiffs are women and because the Rules and settlements at issue target women. The denial of reproductive health care and insurance coverage for that care, however, also affects individuals who may not identify as women, including some gender-nonconforming individuals and transgender men.

and Drug Administration-approved contraceptives guaranteed to them by law, while at the same time relieving employers and universities with religious objections of their obligation to cover contraception in their health insurance plans.

4. Defendant Notre Dame and others mounted legal challenges to the accommodation process. But eight of the nine federal courts of appeals to consider such challenges flatly rejected them—including the Seventh Circuit, twice. The U.S. Supreme Court remanded all these cases to be resolved in a manner that "ensur[es] that women covered by [the entities'] health plans receive full and equal health coverage, including contraceptive coverage." *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016); *see also, e.g.*, *Univ. of Notre Dame v. Burwell*, 136 S. Ct. 2007 (Mem.).

5. Now the Departments seek to eviscerate the contraceptive coverage requirement, to the detriment of Plaintiffs and countless others nationwide. By their actions, the Departments have embarked on a two-tiered effort to do by fiat what the courts had refused to allow: give employers and universities a veto over the legal rights of countless women to obtain coverage for necessary health care.

6. First, on October 6, 2017, the Departments issued two Interim Final Rules that allowed all nongovernmental entities—including for-profit businesses, nonprofits, and universities—to declare themselves exempt from the contraceptive coverage requirement based on religious beliefs, and allowed most such entities to exempt themselves based on so-called moral convictions.[2] The Interim Final Rules also made the accommodation process optional. In other

[2] These Interim Final Rules were issued and went into effect on October 6, 2017, and were published in the Federal Register on October 13. Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (collectively, the "Interim Final Rules" or "IFRs").

words, the Interim Final Rules allowed covered entities to impose their religious and moral beliefs on countless women by preventing employees, students, and their dependents from receiving contraceptive coverage.

7. Second, on October 13, 2017, just one week after issuing the Interim Final Rules, the Departments executed a private settlement agreement with more than 70 entities, including Notre Dame, resolving the signatories' pending legal challenges to the ACA accommodation process, with terms that echoed the Interim Final Rules' unlawful religious and moral exemptions and then extended the scope of those exemptions even further. *See* Exhibit A. In direct contravention of legal requirements and long-standing Department of Justice policy, the Settlement Agreement impermissibly negotiates away the rights of third parties by purporting *permanently* to exempt the signatories from all contraceptive coverage requirements, both past *and future*. Even though the University admits that "most of [the 17,000 people] covered [by its health plans] have no financially feasible alternative but to rely on the University for such coverage,"[3] the Settlement Agreement allows Notre Dame to deny them contraceptive coverage in their regular health plan. The Settlement Agreement also awards the signatories millions of taxpayer dollars in attorneys' fees.

8. On February 7, 2018, Notre Dame—citing the Settlement Agreement as support—declared that it would no longer abide by the contraceptive coverage requirement. The University announced that it would refuse to comply with the accommodation process. Consequently, students and employees would no longer receive coverage for the full range of FDA-approved contraceptives and related services, in contravention of the regulations then in effect. Moreover, while faculty and student insurance policies would cover what they call certain "simple"

[3] Letter to Faculty and Staff by President Rev. John I. Jenkins, C.S.C. (Feb. 7, 2018).

contraceptives, they would be subject to co-payments, coinsurance, and deductibles—in contravention of the ACA itself, the regulations then in effect, and even the October 2017 IFRs (which by then had been enjoined by two federal courts (*see Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017); *California v. HHS*, 281 F. Supp. 3d 806 (N.D. Cal. 2017)). In other words, the University announced that it would impose its own views about contraception on the 17,000 people covered by its health plans. By excluding some methods of contraceptives altogether and imposing cost-sharing on other methods, the University's new policy strips women of the contraceptive coverage guaranteed to them by law and erects financial, administrative, and logistical barriers to contraception.

9. While litigation challenging the IFRs was pending, the Departments issued two Final Rules that made the Interim Final Rules permanent in all material respects.[4] In January 2019, just before the Final Rules were scheduled to take effect, two federal courts preliminarily enjoined them. *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019); *California v. HHS*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019). The U.S. Courts of Appeals for the Third and Ninth Circuits affirmed the preliminary injunctions. *Pennsylvania v. President United States*, 930 F.3d 543, 575-76 (3d Cir. 2019); *California v. U.S. Dep't of Health & Human Servs.,* 941 F.3d 410, 431 (9th Cir. 2019). The government appealed, and the U.S. Supreme Court reversed the judgment of the Third Circuit. The Court held that the Final Rules were not procedurally defective under the APA and that the Departments had statutory authority under the ACA to create religious and moral

[4] These Final Rules were issued on November 7, 2018, and were published in the Federal Register on November 15, 2018. Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (collectively, the "Final Rules" or "Rules").

exemptions to the contraceptive coverage requirement. The Court vacated the preliminary injunctions from the Third and Ninth Circuits on that basis and remanded both cases for further consideration.

10. The Supreme Court did not decide whether the Final Rules are arbitrary and capricious under the APA, or whether the Rules violate the Establishment Clause of the First Amendment. And no court has decided the legality of the Settlement Agreement.

11. Under the Rules and the Settlement Agreement, Plaintiffs and other women have incurred and will continue to incur greater costs to obtain contraception, and have been and will continue to be deterred or prevented from using the most appropriate method of contraception for them. Some women will be unable to obtain contraception altogether. The Rules and the Settlement Agreement deprive Plaintiffs and other women of their right to make reproductive decisions consistent with their own values and beliefs, imposing the religious beliefs of a select few on individuals who may not share those beliefs and reinstating the discrimination against women that the contraceptive coverage requirement addressed. And the Rules and Settlement Agreement are not narrowly tailored to address actual burdens on religious exercise. They thus permit employers and universities to deny women access to contraceptive coverage in violation of the Administrative Procedure Act and the U.S. Constitution.

12. For these reasons and others described below, this Court should vacate and set aside the Rules, enjoin Defendants from enforcing or relying on the Rules, declare the Settlement Agreement between Notre Dame and the Departments void, and enjoin Defendants from enforcing or relying on the Settlement Agreement with respect to Notre Dame and the health plans that it sponsors.

PARTIES

13. Plaintiff Irish 4 Reproductive Health ("I4RH") is an unincorporated association of undergraduate and graduate students in South Bend, Indiana, who attend Notre Dame. The organization's mission is to advocate for reproductive justice on campus and in the surrounding community, including by securing access to insurance coverage for the full range of FDA-approved contraceptive methods and related services, education, and counseling, with no out-of-pocket costs. I4RH promotes human dignity by affording respect to all people to make moral choices about their own lives, including whether and when to have children. I4RH recognizes that sexual health is essential for overall well-being, and that access to reproductive health care, education, and resources is necessary for realizing social, political, and gender equality—both at the University and around the globe. The students who would eventually form I4RH began organizing in the wake of the upheaval and uncertainty over the future of contraceptive coverage at the University. Initially, the founding student members of I4RH came together to protest the University's October 2017 decision to terminate contraceptive coverage, *see infra* ¶¶ 124–25. After the University temporarily reversed that decision in early November 2017, *see infra* ¶131, the students continued to work to improve and expand access to reproductive health care at the University and in the surrounding community. The students formed I4RH on February 7, 2018, in response to the University's letter of that date announcing its plan to terminate coverage for certain methods of contraception, *see infra* ¶ 134–36. Obtaining relief from Defendants' unlawful Settlement Agreement and Rules is essential to realizing I4RH's animating purpose and to further its broader mission of promoting and protecting reproductive health at the University and beyond. Several members of I4RH will be personally harmed by the Settlement Agreement and the Rules. For example:

a. I4RH Member 1 is a graduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. I4RH Member 1 uses an oral contraceptive that she refills every three months to prevent pregnancy. During the 2017-18 school year, I4RH Member 1 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health. Through the accommodation process, Aetna covered the full cost of I4RH Member 1's oral contraceptive. Since the changes to the University's student health plan went into effect on August 15, 2018, I4RH Member 1 has paid coinsurance for her oral contraceptive out of pocket. And though I4RH Member 1 would prefer to use an intrauterine device or contraceptive implant for medical reasons, she is unable to switch to one of these preferred methods because the coinsurance for the device and associated office visits would be prohibitively expensive. I4RH Member 1's health care provider has informed her that the coinsurance for either device alone would cost her $400–500 plus the cost of office visits.

b. I4RH Member 2 is a graduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. From 2010 until June 2018, Member 2 used the NuvaRing, a hormonal contraceptive with no generic alternative, both to prevent pregnancy and to reduce pain during menstruation, which she has experienced since suffering complications from a surgery. During the 2017-18 school year, I4RH Member 2 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health. Through the accommodation process, Aetna covered the full cost of I4RH Member 2's NuvaRing. Beginning August 15, 2018, Member 2

has had to pay coinsurance for her NuvaRing. To avoid this added cost, Member 2 had to switch to a hormonal long-acting intrauterine device while she still had coverage through the accommodation. Since August 15, 2018, Member 2 is subject to cost-sharing for removal or replacement of the IUD and for help with complications should any occur, including the cost of office visits related to her IUD.

c. I4RH Member 3 is a graduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. I4RH Member 3 uses an oral contraceptive that she refills every three months to prevent pregnancy. I4RH Member 3 pays coinsurance for her oral contraceptive out of pocket every time she refills her prescription.

d. All members of I4RH who rely on University-sponsored health insurance for their contraceptive needs are subject to the University's new contraceptive coverage policy. All members of I4RH who rely on University health insurance for their contraceptive needs are now subject to cost-sharing for some contraceptive methods and are being deprived of coverage for other methods. As all members of I4RH enrolled in University-sponsored health insurance are subject to the same illegal University policy and seek the same form of relief, neither the claims asserted nor the relief requested requires the participation of individual members in this lawsuit.

14. Plaintiff Natasha Reifenberg is a recent graduate of the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled as a dependent in the University's faculty and staff health plan. Ms. Reifenberg relies on that plan for all her medical needs. Ms. Reifenberg previously received coverage for her contraception without cost-sharing

through the accommodation process. Ms. Reifenberg has used oral contraceptives in the past and later had need to switch to a long-acting, reversible form of contraception going forward. Ms. Reifenberg was unable to obtain a long-acting form of contraception before the University's revised employee plan went into effect on July 1, 2018, because her OB-GYN had relocated, and she had to undertake the process of finding a new doctor to provide this service. Ms. Reifenberg has since chosen an OB-GYN and arranged for insertion of a long-acting intrauterine device. The cost of the device and the cost of the office visit for the insertion procedure were only 85% covered through Ms. Reifenberg's health plan, and both were subject to a deductible. Ms. Reifenberg is now subject to cost-sharing for removal or replacement of the IUD and for help with complications should any occur, including the cost of office visits related to her IUD.

15. Plaintiff Jane Doe 1 is a graduate student at the University and lives in Granger, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. Doe 1 uses an oral contraceptive that she refills every three months to prevent pregnancy. During the 2017-18 school year, Doe 1 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health. Through the accommodation process, Aetna previously covered the full cost of Doe 1's oral contraception. Since the changes to the University's student health plan went into effect on August 15, 2018, Doe 1 has paid coinsurance for her oral contraceptive out of pocket.

16. Plaintiff Jane Doe 2 is the daughter of a professor at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled as a dependent in the University's faculty and staff health plan and relies on that plan for all her medical needs, including contraceptives. Doe 2 received coverage for her contraception without cost-sharing through the

accommodation process until July 1, 2018. Doe 2 uses an oral contraceptive both for non-contraceptive medical purposes and to prevent pregnancy. Through the accommodation process, OptumRx previously covered the full cost of Doe 2's prescription. Since the changes to the University's employee plan went into effect on July 1, 2018, Doe 2 has paid a copayment for her oral contraceptive out of pocket.

17. Plaintiff Jane Doe 3 is a recent professional school graduate student and lives in Illinois. She is a woman of child-bearing age who is enrolled in Notre Dame's faculty and staff health plan and relies on that plan for all her medical needs, including contraceptives. Doe 3 received coverage for her contraception without cost-sharing through the accommodation process until July 1, 2018. Doe 3 has been relying on oral contraception since 2013 to prevent pregnancy, to control acne, and to regulate her menstrual cycle. Through the accommodation process, OptumRx previously covered the full cost of Doe 3's oral contraception. Since the changes to the University's employee plan went into effect on July 1, 2018, Doe 2 has paid a copayment for her oral contraceptive out of pocket.

18. The Government Defendants are agencies and appointed officials of the Executive Branch of the United States who are responsible for issuing and enforcing the contraceptive coverage requirement under the ACA and the Rules and are parties to the Settlement Agreement.

a. Defendant HHS is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.

b. Defendant Department of Labor is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.

c. Defendant Department of Treasury is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.

d. Defendant Alex M. Azar II is the Secretary of Health and Human Services and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of Health and Human Services.

e. Defendant Eugene Scalia is the Secretary of Labor and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of Labor.

f. Defendant Steven Mnuchin is the Secretary of the Treasury and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of the Treasury.

19. Defendant University of Notre Dame is a private university located in Notre Dame, Indiana, and executed the Settlement Agreement at issue in this action. The University's health plans cover more than 17,000 people, including employees, students, and dependents.

JURISDICTION AND VENUE

20. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361, as this action arises under the Constitution and laws of the United States. This Court has jurisdiction to render declaratory and injunctive relief under 28 U.S.C. §§ 2201 and 2202, 5 U.S.C. § 702, and Fed. R. Civ. P. 57 and 65.

21. Venue is proper in this district under 28 U.S.C. § 1391(e). The University is located in this judicial district, and a substantial part of the events, actions, or omissions giving rise to these claims are occurring in this judicial district. The Government Defendants are United States agencies and officers sued in their official capacities. I4RH and Does 1 and 2 reside in this judicial district, and all the Plaintiffs get their health coverage through the University student and faculty plans.

FACTUAL BACKGROUND

A. The Importance of Contraception

22. Regardless of their religious affiliation, 99% of women of reproductive age who have had sexual intercourse report using at least one form of contraception at some point in their lives. K. Daniels, W.D. Mosher & J. Jones, *Contraceptive Methods Women Have Ever Used: United States, 1982–2010*, National Health Statistics Reports, 2013, No. 62.

23. Contraception is critical to women's and children's health.

24. Research has also shown that access to contraception improves the social and economic status of women.

25. Contraception reduces unintended pregnancies, the need for abortion, adverse pregnancy outcomes, and negative health consequences to women and children. Inst. of Med., *Clinical Preventive Services for Women, Closing the Gaps*, ("IOM Report") at 102-109 (July 19, 2011).[5]

26. Contraception prevents unintended pregnancy, which can have severe negative consequences for both women and their children.

27. During an unintended pregnancy, a woman is more likely to receive delayed or no prenatal care, to be depressed, and to suffer from domestic violence. *Id.* at 103.

28. An unintended pregnancy may result in preterm birth and low birth weight. *Id.*

29. Contraception allows women to postpone pregnancy and optimally space their children to avoid adverse consequences (*e.g.*, low birth weight, premature birth) associated with more than one pregnancy in 18 months. *Id.* at 103.

[5] As of July 1, 2015, IOM changed its name to the National Academy of Medicine. It is part of the National Academies of Sciences, Engineering, and Medicine, which advise the nation on matters of science, technology, and health.

30. Contraception is highly effective in treating and preventing certain health conditions.

31. Contraception decreases the risk of certain cancers (such as endometrial and ovarian cancer), manages menstrual disorders, and protects against pelvic inflammatory disease and some breast diseases. *Id.* at 107.

32. In addition, pregnancy may be dangerous to some women with certain chronic medical conditions, such as diabetes, obesity, pulmonary hypertension, or heart disease. *Id.* at 103.

33. When pregnancy is contraindicated, women may need contraception to delay pregnancy until their medical conditions are under control or to prevent pregnancy throughout their lives. *Id.* at 103-4.

34. In a national study conducted in 2017, 22% of women age 18-44 who use contraception said that they used contraceptives to manage a medical condition and prevent pregnancy; 13% used contraceptives solely to manage a medical condition. Caroline Rosenzweig et al., Kaiser Family Found., *Women's Sexual and Reproductive Health Services: Key Findings from the 2017 Kaiser Women's Health Survey* 3 (2018), http://files.kff.org/attachment/Issue-Brief-Womens-Sexual-and-Reproductive-Health-Services-Key-Findings-from-the-2017-Kaiser-Womens-Health-Survey.

35. Women also rely on contraception to prevent pregnancy following a sexual assault and to prevent or delay pregnancy during public-health crises, such as the outbreak of the COVID-19 and Zika viruses. *See* Nat'l Women's Law Ctr., Access to Contraceptives During the COVID-19 Pandemic and Recession (Jul. 2020), https://bit.ly/3aDb7ZG.

36. Access to contraception has been proven to advance women's equality and participation in the social and economic life of this country.

37. Studies show that contraception is directly linked to women's increased educational and professional opportunities and increased lifetime earnings. *See, e.g.,* Jennifer J. Frost & Laura Duberstein Lindberg, *Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics*, 87 Contraception 465, 467 (2013); Adam Sonfield, *et al*., Guttmacher Inst., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children* (2013), http://www.guttmacher.org/pubs/social-economic-benefits.pdf.

38. The FDA Office of Women's Health's Birth Control Guide identifies 17 methods of birth control that are female controlled. *See* U.S. Food & Drug Admin., Birth Control Guide, https://www.fda.gov/media/135111/download (current as of Feb. 11, 2020). Contraceptives vary in effectiveness, duration, side effects, methods of action, and ease of use. Nonetheless, all new contraceptive drugs and devices (just like other drugs and devices) must receive approval from the FDA, which requires showing through rigorous scientific testing that they are safe and effective.

39. Not all women can tolerate all forms of contraception, and as the FDA has said: "No one product is best for everyone." U.S. Food & Drug Admin., Birth Control Guide, https://www.fda.gov/media/135111/download.

40. Thus, women need insurance coverage of all FDA-approved methods, contraceptive counseling, and education to find the most appropriate method for them.

41. Women using contraception also need insurance coverage for associated services that assist them in understanding their contraceptive options, such as counseling with a health-care provider to ensure the effectiveness and safety for them of their chosen form of contraception.

B. Cost Barriers Impede Access to Contraception

42. Cost is often an impediment to women's obtaining contraception.

43. Cost may influence women to avoid more effective but more expensive methods of contraception or to forgo contraceptives altogether.

44. Without insurance coverage, the most effective methods of contraception carry large up-front costs that make them unaffordable for many women.

45. For example, without coverage, an IUD may cost up to $1,300.

46. Studies show that the costs associated with contraception, even when small, lead women to forgo contraception completely, to choose less effective methods, or to use it inconsistently. *See, e.g.*, Guttmacher Inst., *A Real-Time Look at the Impact of the Recession on Women's Family Planning and Pregnancy Decisions* 5 (Sept. 2009), http://www.guttmacher.org/pubs/RecessionFP.pdf. This is particularly true during times of economic uncertainty. *Id.*

47. When costs lead women to forgo contraception completely, to choose less effective methods, or to use it inconsistently, there is an increased risk of unintended pregnancy. *See, e.g.*, Rachel Benson Gold, *The Need for and Cost of Mandating Private Insurance Coverage for Contraception*, 1 Guttmacher Rep. on Pub. Pol'y 5, 6 (1998).

48. Cost barriers to contraception in and of themselves not only threaten the economic security of women and their families, but in undermining access to contraception they also threaten women's long-term financial well-being, job security, workforce participation, and educational attainment.

C. The ACA and the Contraceptive Coverage Requirement

49. Since the ACA was passed by Congress and signed by the President in March 2010, it has extended accessible and affordable health-insurance coverage to millions of Americans and reduced sex discrimination in health care.

50. To ensure that health insurance remains accessible and affordable, the ACA

contains a number of critical provisions.

51. Among these provisions is the requirement that group health plans include insurance coverage for preventive health services with no cost-sharing. 42 U.S.C. § 300gg-13(a).

52. To protect women's health, to ensure that women do not pay more for insurance coverage, and to advance women's equality and well-being, Congress included the Women's Health Amendment in the ACA.

53. The Women's Health Amendment requires insurance plans to cover certain women's preventive health services without cost-sharing. 42 U.S.C. § 300gg-13(a)(4).

54. Before the ACA was enacted, insurers had not consistently covered women's preventive health services.

55. Women had historically paid much more in out-of-pocket health costs, based largely on significant costs for basic and necessary preventive care; and in some instances, women were unable to obtain this care at all because of cost barriers.

56. Congress included the Women's Health Amendment in the ACA to help alleviate the "punitive practices of insurance companies that charge women more and give [them] less in a benefit" and to combat other forms of widespread sex discrimination in the health-insurance market. 155 Cong. Rec. S12,021, S12,026 (daily ed. Dec. 1, 2009) (statement of Sen. Mikulski).

57. Congress specifically intended for the Women's Health Amendment to improve women's health by providing "affordable family planning services" to "enable women and families to make informed decisions about when and how they become parents." 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken).

58. Under the Women's Health Amendment, Congress required the Health Resources and Services Administration ("HRSA"), a component of HHS, to adopt guidelines on the women's

preventive-care services that must be covered under the ACA without cost-sharing.

59. Before issuing the Guidelines, HRSA commissioned the Institute of Medicine (now the National Academy of Medicine) to convene a committee of experts on women's health, adolescent health, disease prevention, and evidence-based guidelines, to conduct a comprehensive review of women's preventive-health needs and to produce a report. *See* IOM Report (2011).

60. Based on detailed findings—including findings that access to contraception reduces unintended pregnancies, abortions, adverse pregnancy outcomes, and negative health consequences to women and children, and that even small cost-sharing requirements significantly reduce the use of contraception—this expert committee of the Institute of Medicine recommended that HRSA include the "full range of Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity" as one of eight critical preventive services for women. *Id.* at 109-110.

61. In August 2011, HRSA adopted the required Guidelines, which accepted and implemented in full the Institute of Medicine's recommendation on contraception and seven other preventive services for women. *See* HRSA, *Women's Preventive Services Guidelines*, http://hrsa.gov/womens-guidelines.

62. To date, HRSA has not removed any services from the list set forth in the Guidelines regarding which women's preventive services must be covered for a group or individual health plan to comply with the ACA: Contraceptive methods and counseling remain required benefits. *See* HRSA, *Women's Preventive Services Guidelines*, http://hrsa.gov/womens-guidelines.[6]

[6] Following issuance of the Interim Final Rules, language was added in a footnote to the "contraceptive methods and counseling" line of the Guidelines with the text of the Religious and

63. As recently as December 2016, a panel of experts convened by the American College of Obstetricians and Gynecologists, through a cooperative agreement with HRSA, reaffirmed the importance of the ACA's contraceptive coverage requirement. Women's Preventive Services Initiative, *Recommendations for Preventive Services for Women* (2016), https://www.womenspreventivehealth.org/final-report/.

64. After the IOM Report and years of comments, the three departments primarily responsible for implementing the Women's Health Amendment—the Departments of Health and Human Services, Labor, and Treasury—finalized the preventive-services regulations, which required coverage of all the women's preventive-care services outlined in the Guidelines, including all FDA-approved methods of contraception and related education and counseling for women. *See* 45 C.F.R. § 147.130(a)(1)(iv) (HHS); 29 C.F.R. § 2590.715-2713(a)(1)(iv) (Labor); 26 C.F.R. § 54.9815-2713(a)(1)(iv) (Treasury).

65. The Departments concluded that it is critical to extend "any coverage of contraceptive services under the HRSA Guidelines to as many women as possible." 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

66. In various rulemakings, the Departments explained that they included contraceptive services in these regulations based on the Departments' factual findings regarding the benefits and efficacy of contraception and the critical importance of contraceptive coverage without cost-sharing for women's health and equality. The Departments previously found that:

Moral Exemption language. *Id.* The Guidelines on HRSA's website have continued to include this footnote, and thereby impermissibly tell entities that they may unilaterally opt out of providing contraceptive coverage, even while the enabling Rules were subject to two nationwide preliminary injunctions.

a. "[W]omen have unique health care needs" and "[s]uch needs include contraceptive services." 78 Fed. Reg. 39,872.

b. Contraceptives "reduc[e] the number of unintended pregnancies." *Id.*

c. "[C]ontraceptive use helps women improve birth spacing and therefore avoid the increased risk of adverse pregnancy outcomes that comes with pregnancies that are too closely spaced." *Id.*

d. "Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne)." *Id.*

e. "It is for a woman and her health care provider in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive services in general or any particular contraceptive service." *Id.*

f. Before the ACA, disparities in health coverage "placed women in the workforce at a disadvantage compared to their male coworkers," and "[r]esearch shows that access to contraception improves the social and economic status of women." *Id.* at 39,873.

g. "Research also shows that cost sharing can be a significant barrier to access to contraception" and "eliminating cost sharing is particularly critical to addressing the gender disparity [in health coverage]." *Id.*

h. "Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating [the gender] disparity [in health coverage] by allowing women to achieve equal status as healthy and productive members of the job force." 77 Fed. Reg. 8,725, 8,728 (Feb. 15, 2012).

67. HRSA also explained that contraception is "necessary for women's health and well-being." HRSA, *Women's Preventive Services Guidelines*, www.hrsa.gov/womens-guidelines.

D. Religious Objections to Contraceptive Coverage, and the Accommodation Process

68. Houses of worship were and continue to be exempt from the ACA's contraceptive coverage requirement.

69. Certain religiously affiliated employers and universities that did not qualify for the house-of-worship exemption objected to providing health-insurance coverage for contraception to employees and students and their dependents.

70. To accommodate these entities' objections while still ensuring that women at the entities receive access to seamless, affordable contraceptive coverage, the Departments developed and made available an "accommodation" process for certain religiously affiliated nonprofit institutions. *See* 78 Fed. Reg. 39,870, 39,871 (July 2, 2013).[7]

71. When revising their regulations to create the accommodation process, the Departments reiterated their finding that "providing more women broad access to recommended preventive services, including contraceptive services, without cost sharing" advances "compelling public health and gender equity interests." 78 Fed. Reg. 39,873. Specifically, the Departments explained: "[T]he contraceptive coverage requirement serves two compelling governmental interests. The contraceptive coverage requirement furthers the government's compelling interest

[7] While the term "accommodation" has been used as a shorthand in this context to mean the ability of certain qualifying employers and universities to refuse to provide the contraceptive coverage on giving notice (so that the government may ensure that separate payments for contraception will be made by the entity's insurer or third-party administrator), and the term "exemption" has been used to mean the ability to opt out of providing the coverage without giving notice (leaving employees and students without coverage through their regular insurance plan), a "religious accommodation" is merely an exemption from a general legal requirement on religious grounds. *See generally Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327 (1987).

in safeguarding public health by expanding access to and utilization of recommended preventive services for women. . . . The government also has a compelling interest in assuring that women have equal access to health care services. Women would be denied the full benefits of preventive care if their unique health care needs were not considered and addressed. . . . The contraceptive coverage requirement helps remedy this problem [of gender disparities in health outcomes] by helping to equalize the provision of preventive health care services to women and, as a result, helping women contribute to society to the same degree as men." 78 Fed. Reg. 39,887.

72. The Departments also determined that this accommodation process poses "no burden on any religious exercise," 78 Fed. Reg. 39,887, and in all events is the "least restrictive means" of furthering their compelling interests in the contraceptive coverage requirement, *id.* The Departments explained that they considered all proposed alternatives suggested by commenters, "and it was determined that they were not feasible and/or would not advance the government's compelling interests as effectively." 78 Fed. Reg. 39,888.

73. The Departments made the accommodation final only after reviewing a total of approximately 600,000 comments on the Advance Notice of Proposed Rulemaking and Notice of Proposed Rulemaking.

74. The accommodation was later extended to certain closely held, for-profit entities with religious objections to contraception, in response to the U.S. Supreme Court's decision in *Burwell v. Hobby Lobby Stores, Inc*., 134 S. Ct. 2751 (2014). *See* 80 Fed. Reg. 41,318 (July 14, 2015).

75. The Departments made the extension of the accommodation final only after reviewing approximately 75,000 comments in response to the related Notice of Proposed Rulemaking.

76. The accommodation allows an objecting entity either to sign a form (EBSA Form 700) stating its objection to providing contraceptive coverage and submit that form to the entity's insurance company, or otherwise to notify the federal government of its objection. 26 C.F.R. § 54.9815-2713A (2015).

77. After this notification, the insurance company or third-party administrator provides or arranges for separate payments for contraceptive services directly to the affected women, without cost-sharing. *Id.*

78. Thus, under the accommodation, an objecting entity is entirely relieved of "contracting, arranging, paying, or referring for contraceptive coverage," while the women who are employees, students, or dependents receive the required coverage from their regular insurance company, without cost-sharing.

79. A number of entities that were eligible for the accommodation nevertheless challenged it, contending that merely filling out the accommodation form or notifying the government of their objection violated the Religious Freedom Restoration Act ("RFRA") and the U.S. Constitution.

80. The objecting employers and universities argued that providing notification in order to opt out of the ACA's contraceptive coverage requirement is a "trigger" to women's receiving contraceptive coverage, even though the objecting entities are not required to provide the coverage.

81. Several of these entities filed lawsuits. The Departments repeatedly maintained in litigation their position that the accommodation process does not substantially burden religious exercise.

82. Eight of the nine federal courts of appeals to consider these cases flatly rejected the challenges. *See, e.g., Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't Health &*

Human Servs., 818 F.3d 1122, 1148–51 (11th Cir. 2016); *Little Sisters of Poor House v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs*., 778 F.3d 422 (3d Cir. 2015);; *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449, 459–63 (5th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 611–15 (7th Cir. 2015); *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 218–26 (2d Cir. 2015); *Mich. Catholic Conference & Catholic Family Servs. v. Burwell*, 807 F.3d 738, 749–50 (6th Cir. 2015); *Priests for Life v. U.S. Dep't of Health & Human Servs*., 772 F.3d 229 (D.C. Cir. 2014); *but see Dordt Coll. v. Burwell*, 801 F.3d 946 (8th Cir. 2015).

83. The U.S. Court of Appeals for the Seventh Circuit held that the accommodation process does not substantially burden Notre Dame's exercise of religion and therefore does not violate RFRA. *See Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 607 (7th Cir. 2015), *vacated on other grounds*, 136 S. Ct. 2007 (2016); *Univ. of Notre Dame v. Sebelius*, 743 F.3d. 547, 554 (7th Cir. 2014), *vacated on other grounds*, 135 S. Ct. 1528 (2015); *see also Grace Sch. v. Burwell*, 801 F.3d 788, 791 (7th Cir. 2015), *vacated on other grounds*, 136 S. Ct. 2011 (2016); *Wheaton Coll. v. Burwell*, 791 F.3d 792, 795 (7th Cir. 2015).

84. The U.S. Supreme Court granted certiorari in seven of the cases and ultimately vacated and remanded *all* the cases with the instruction that the parties "should be afforded an opportunity to arrive at an approach going forward that "accommodates [the entities'] religious exercise while at the same time ensuring that women covered by [the entities'] health plans receive full and equal health coverage, including contraceptive coverage." *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016) (citation and internal quotation marks omitted).

85. On July 22, 2016, in light of the Supreme Court's decision in *Zubik*, the Departments issued a Request for Information ("RFI") to solicit from interested parties comments

on "whether there are alternative ways (other than those offered in current regulations) for eligible organizations that object to providing coverage for contraceptive services on religious grounds to obtain an accommodation, while still ensuring that women enrolled in the organizations' health plans have access to seamless coverage of the full range of Food and Drug Administration-approved contraceptives without cost sharing." 81 Fed. Reg. 47,741 (July 22, 2016).

86. After reviewing approximately 54,000 public comments, the federal government concluded on January 9, 2017, that "the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that affected women receive full and equal health coverage, including contraceptive coverage," so "the Departments continue to believe that the existing accommodation regulations are consistent with RFRA . . . ." Dept. of Labor, FAQs About Affordable Care Act Implementation Part 36, at 4-5 (Jan. 9, 2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

87. Meanwhile, the various *Zubik* cases were held in abeyance while the parties attempted to work out resolutions to the litigation.

88. According to court filings in those cases, the federal government met numerous times with entities challenging the coverage requirement to discuss resolution of the claims concerning the accommodation process.

89. Although Notre Dame students were intervenors in the University's challenge to the contraceptive coverage requirement, they were not permitted to participate in that process (*see* Status Report of Intervenors-Appellees at 2, *Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir. Oct. 2, 2017)).

E. The Interim Final Rules and Final Rules

90. President Trump issued an Executive Order on May 4, 2017, titled "Promoting Free Speech and Religious Liberty," directing issuance of the type of Rules challenged here. Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017).

91. The Order states that, regarding the "Conscience Protections with Respect to Preventive-Care Mandate," "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code."

92. Without any public notice and comment or other pre-promulgation mechanism for receiving input from the public, the Departments issued the Interim Final Rules on October 6, 2017.

93. The Interim Final Rules took effect immediately.

94. Only after the Interim Final Rules went into effect did the Departments solicit comments from the public.

95. In December 2017, two district courts entered nationwide preliminary injunctions temporarily blocking the Interim Final Rules from taking effect. *See Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017); *California v. HHS*, 281 F. Supp. 3d 806 (N.D. Cal. 2017). Both decisions were appealed.

96. Despite two federal court injunctions prohibiting the Interim Final Rules from taking effect, the Departments issued Final Rules on November 7, 2018, with an effective date of January 14, 2019. The Final Rules finalize the Interim Final Rules in all material respects and are as substantively unlawful as the Interim Final Rules.

97. The Final Rules, like the IFRs, dramatically expand the scope of the exemption and

the types of entities that can claim it, allowing the covered entities to choose whether they will participate in the accommodation process or whether they will instead affirmatively prevent employees and students from receiving contraceptive coverage.

98. The latter approach has the effect of denying Plaintiffs and other women coverage to which they are otherwise legally entitled.

99. The Final Rules, like the IFRs, broaden the entities eligible for an exemption so that almost any university, nonprofit, for-profit business (whether publicly or privately held), or other nongovernmental employer may refuse to cover contraception in its group health plans without notifying the government.

100. Through the Final Rules, like the IFRs, the Departments also impermissibly attempt to broaden the permissible grounds for seeking the exemption, from sincerely held religious beliefs to sincerely held religious beliefs or sincerely held moral convictions.

101. The Final Rules, like the IFRs, make optional the previously required accommodation process for objecting entities, which was designed to ensure that employees and students would continue to receive seamless contraceptive coverage.

102. Under the Final Rules, like the IFRs, an employer, university, or insurance issuer may claim an exemption and deny coverage, so that the insureds will no longer have seamless contraceptive coverage.

103. The Final Rules lack adequate justification.

104. The Rules exempt virtually all nongovernmental employers and universities with religious or moral objections to the contraceptive coverage requirement—even those who have no objection to the accommodation process and have not asserted, much less demonstrated, a substantial burden on their religious exercise.

105. And the Rules abandon without reasoned explanation HHS's factual findings that the accommodation poses "no burden on any religious exercise" and that there are no feasible alternatives to the accommodation process. 78 Fed. Reg. 39,887–88; *see also supra* ¶¶ 72, 86.

106. The Final Rules also fail to account for the devastating impact on the health, economic security, equality, and autonomy of people who are denied contraceptive coverage. *See infra* Part H.

107. The Rules abandon, without reasoned explanation, HHS's prior factual findings regarding the benefits of contraception to women's health and equality, as well as HHS's conclusion that the government has "compelling public health and gender equity interests" in ensuring coverage of contraception without cost-sharing. *See supra* ¶¶ 65–67, 71. Instead, the Departments reproduce, without analysis, scientifically debunked assertions from commenters that purport to question the efficacy, safety, and importance of contraception, ignoring that the FDA has, after rigorous scientific testing, approved contraceptive drugs and devices as safe and effective. 83 Fed. Reg. at 57,552–57,555; *see also* Comments of Am. Coll. of Obstetricians & Gynecologists, the American Academy of Pediatrics, and the Society for Adolescent Health and Medicine, CMS–9940–IFC, at 2 (Dec. 5, 2017) ("Policies that affect individuals' access to health care should have a positive impact on public health, and be based on science, not on falsehoods that are not supported by medical evidence. . . We oppose public policy that deviates from accepted science and public health evidence, as well as any non-scientific prohibitions on essential care.").

108. Likewise, in citing data questioning the benefits and risks of contraception, the Departments ignore without any explanation—reasoned or otherwise—their previous determination that "[i]t is for a woman and her health care provider," not the Departments, "in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive

services in general or any particular contraceptive service." 78 Fed. Reg. 39,872.

109. Critically, the Rules ignore the substantial empirical and scientific data supporting the Departments' previous findings regarding the benefits and effectiveness of contraception and contraceptive coverage—data and findings that were also submitted in comments opposing the Rules' expansive exemptions, including by leading medical organizations, *see supra* ¶ 107.

110. The Rules also entirely fail to consider the serious reliance interests at stake. Nationwide, women and others who can become pregnant have chosen universities, employers, health plans, and their method of contraception with the understanding that their contraception would be covered.

111. Finally, the Departments' regulatory-impact analysis fails to consider the actual costs of the Rules. Despite the Departments' assertion that neither rule would be economically significant, the Office of Management and Budget classified the Rules as a "significant regulatory action" (*see* Section 3(f)(4) of Executive Order 12,866) because they raise "novel or legal policy issues"—thus triggering the requirement of a regulatory-impact analysis. The Departments' regulatory-impact analysis disregards significant direct and indirect costs identified by commenters, in violation of Executive Order 12,866. HHS also ignores instructions from both the Office of Management and Budget's Circular A-4 on Regulatory Analysis (2003) and HHS's own Guidelines for Regulatory Impact Analysis (2016), which detail best practices for assessing costs and benefits in regulatory-impact analyses and require that agencies account for and quantify both direct and indirect health costs to the fullest extent practicable. Yet HHS failed to account for the full scope of the Rules' costs to women and others who will lose contraceptive coverage—not only the financial costs, but also the adverse effects on the health, economic security, equality, and autonomy of patients who lose or are delayed in access to contraception as a result of increased cost and other

barriers. HHS has failed to acknowledge that these are legitimate and actual costs of the Rules and failed to incorporate them into its cost-benefit analysis.

F. The Settlement Agreement

112. On October 13, 2017, just one week after the Departments issued the Interim Final Rules, and the same day that the Interim Final Rules were published in the Federal Register, the Government Defendants executed the Settlement Agreement, which purported to resolve several pending cases challenging the accommodation process.

113. The Government Defendants executed the Settlement Agreement with Notre Dame, disposing of the University's ongoing legal dispute. The Settlement Agreement also resolved separate legal challenges with more than 70 other private entities.

114. Among other terms, the Settlement Agreement purports to exempt Notre Dame and the health plans that it sponsors from complying with either the existing contraceptive coverage requirement or any "materially similar regulation or agency policy" in the future (Exhibit A at 4).

115. The Settlement Agreement states that "[n]o person may receive [contraceptive coverage] as an automatic consequence of enrollment in any health plan sponsored by Plaintiffs" (Exhibit A at 4).

116. The Settlement Agreement also retroactively rescinds penalties for noncompliance with the contraceptive coverage requirement, providing that no fines should have been assessed (Exhibit A at 6).

117. By these provisions, the Government Defendants purport to grant private entities, including Notre Dame, a contractual right to deny contraceptive coverage to women who rely on their health plans.

118. As a justification for this unlawful action, the Settlement Agreement relied on "the

new regulations," notwithstanding that those Interim Final Rules were themselves unlawful (Exhibit A at 2).

119. The Settlement Agreement further awards the private entities $3 million in costs and fees for their legal counsel, the law firm Jones Day (Exhibit A at 7).

120. Despite repeated requests by the students who intervened in the University's lawsuit to be included in settlement negotiations, the intervenors were excluded from all settlement discussions and were never informed by either the Defendant University or the Government Defendants that a settlement agreement had been negotiated or executed. *See, e.g.*, *Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir.), Status Report of Intervenors-Appellees at 2, (filed Oct. 2, 2017), Status Report of Intervenors-Appellees, Dkt. 152 (filed Aug. 31, 2017).

121. No court was informed of, reviewed, or judicially confirmed the Settlement Agreement.

122. Neither the U.S. Department of Justice nor any of the Defendant agencies issued a public press release announcing the Settlement Agreement.[8]

123. Notre Dame voluntarily dismissed its lawsuit concerning the contraceptive coverage requirement on October 19, 2017, less than two weeks after the Interim Final Rules were issued, and just days after executing the secret Settlement Agreement, although neither Plaintiffs here nor the student-intervenors in Notre Dame's suit were informed about or aware of the Settlement Agreement at that time, and notwithstanding that their rights were directly affected

[8] *See* U.S. Dep't of Justice, Justice News, https://www.justice.gov/news (listing all press releases and revealing that no release was issued about the Settlement Agreement); U.S. Dep't of Health & Human Servs., 2017 News Releases, https://www.hhs.gov/about/news/2017-news-releases/index.html#October (same); U.S. Dep't of Labor, Newsroom, https://www.dol.gov/newsroom/releases/date/2017/October (same); U.S. Dep't of Treasury, Press Releases, https://home.treasury.gov/news/press-releases (same).

thereby. *See Univ. of Notre Dame v. Sebelius*, No. 13-cv-1276 (N.D. Ind.); *Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir.) (appeal dismissed October 17, 2017).

G. Notre Dame's Changes to Contraceptive Coverage

124. On October 27, 2017, Notre Dame announced in e-mails to students, faculty, and staff its intention to withdraw contraceptive coverage from its health plans beginning in the new plan years.

125. After the University's October 27 announcement, students began to organize in response to the University's decision to withdraw contraceptive coverage.

126. Students who would soon form Plaintiff I4RH collected 516 signatures from undergraduate students, graduate students, faculty, and alumni on a statement condemning the University's decision to withdraw contraceptive coverage.

127. During this same period, individuals covered by Notre Dame's health plans—including some of the Plaintiffs in this case[9]—filed lawsuits against the Departments, challenging the Interim Final Rules that had given rise to the University's announced policy changes.

128. Several Notre Dame students filed a lawsuit in this Court. *Shiraef v. Hargan*, 3:17-cv-817 (N.D. Ind.) (filed October 31, 2017).

129. Two other Notre Dame students, along with a national student association, filed a lawsuit in the U.S. District Court for the District of Columbia. *Medical Students for Choice v. Wright*, 1:17-cv-02096, (D.D.C.) (filed on October 10, 2017).

130. Following public expression of serious concerns from students, alumni, and faculty, the University soon reversed course on its decision to terminate contraceptive coverage.

131. In early November 2017, the University sent e-mails to students, faculty, and staff

[9] The plaintiffs in these prior suits included Plaintiffs Natasha Reifenberg and Jane Doe 2.

announcing that it would "not interfere" with the provision of contraceptive coverage to students by Aetna or to faculty and staff by Meritain Health and OptumRx.

132. In reliance on Notre Dame's statements that it would "not interfere" with the provision of contraceptive coverage by the insurance companies, the plaintiffs in the cases identified in Paragraphs 128 and 129 filed notices of voluntarily dismissal.

133. The Courts granted voluntary dismissal of the District of Columbia and Northern District of Indiana cases without prejudice on February 6 and 7, 2018.

134. Also on February 7, immediately after the dismissal orders were entered, the University again reversed course, announcing that it would, in fact, be terminating insurance coverage for certain FDA-approved methods of contraception. For employees, the change would take effect on July 1, 2018, in the middle of the plan year; for students, the change would take effect beginning with the new plan year, in August 2018.

135. In justifying this change in coverage, the University publicly invoked the Settlement Agreement as independent authority.[10]

136. As explained in two letters sent on February 7, 2018, by Notre Dame's President, John Jenkins, to "Aetna Student Health Enrollees" and to "Faculty and Staff," a "favorable" settlement with the U.S. government purportedly gave "the University, its insurers and third party administrators the option of an exemption from providing" coverage for all FDA-approved methods of contraception without cost-sharing. Jenkins's letters did not state which contraceptive methods would continue to be covered and which would not.

137. Following the February 7 announcements, students, faculty, and staff were left

[10] The University has subsequently also stated that Notre Dame considers itself "fully exempt from the [contraceptive coverage] mandate" under "current regulations." ECF No. 35-1 at 8.

guessing whether their methods of contraception would remain covered.

138. On March 25, 2018, University Health Services circulated a "Health Care Coverage Update" to students, which directed students to review a "Frequently Asked Questions about Contraceptive Coverage" ("FAQ") webpage for more information about the changes to contraceptive coverage in the student health plan.

139. The FAQ explains that the University will provide no coverage for copper IUDs or emergency contraceptives.

140. The FAQ also explains that even though the University said that it will "cover" certain methods of contraception, it will require students to pay sums out-of-pocket for any covered contraceptive method, in direct contravention of the Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), and implementing regulations.

141. According to the FAQ, students must pay the same out-of-pocket costs for contraception covered by the plan as for other prescription drugs.

142. On April 30, 2018, Plaintiff I4RH sent Notre Dame President Jenkins an "insurance clarity petition" with more than 100 signatures from Notre Dame undergraduates, graduate students, alumni, faculty, and staff, demanding additional details about the University's announced changes to contraceptive coverage.

143. The petition also expressed disapproval of the change in policy and the "lack of transparency that has characterized the [university] administration's every move on this issue since October 2017."

144. On May 4, 2018, Ann Firth, Chief of Staff in the Notre Dame Office of the President, responded to I4RH that the University would not issue any more details about the Aetna student health plan until July 1, which was after matriculating and returning students would already have

to commit to their programs.

145. Throughout the course of the two years since Notre Dame's announcement, the University has been relying on the Settlement Agreement and Rules to deny certain contraceptive coverage altogether and/or to deny any contraceptive coverage without cost-sharing. Plaintiffs and others have thus not had access to insurance coverage of some preferred methods of FDA-approved contraception. For example, at least one member of I4RH was unable to obtain either a hormonal IUD or implant, their preferred methods of contraception, because the cost would be "prohibitively expensive." *See supra* ¶ 13(a). To the extent Plaintiffs and others on Notre Dame's health plans have been able to obtain coverage contraceptive coverage, they have been required to do so with a co-pay and/or subject to a deductible.

H. Effect of the Rules and Settlement Agreement

146. The expanded exemptions in the Rules effectively nullify the contraceptive coverage requirement, including regulations that took over six years to promulgate and involved multiple consultations with expert committees as well as six rounds of notice-and-comment rulemaking in the form of Advanced Notices of Proposed Rulemaking, Notices of Proposed Rulemaking, Interim Final Rules with comment periods, and Requests for Information, which together elicited more than 725,000 comments.

147. The Settlement Agreement and other similar settlements, separate and apart from the Rules, constitute a general policy not to enforce the contraceptive coverage requirement, and effectively nullify the contraceptive coverage requirement as to its signatories and unknown related entities offering coverage through the health plan of a signatory. Indeed, the Government Defendants have refused to substantively defend *all* litigation challenging the contraceptive coverage requirement.

148. The expanded exemptions in the Rules allow virtually any employer or university to evade the contraceptive coverage requirement and thereby to harm women by imposing their religious and moral views on employees and students.

149. The Rules, the Settlement Agreement, and any other similar settlements create a major change in law.

150. The Rules, the Settlement Agreement, and any other similar settlements establish and impose one subset of religious views while denying health care to those with different beliefs.

151. The result is that Plaintiffs and other women are denied coverage for contraception and related services and thus are harmed.

152. The expanded exemptions jeopardize the health, economic security, and equality of more than 62 million women who currently have coverage for all FDA-approved contraceptive methods and related education and counseling without out-of-pocket costs. *See* Nat'l Women's Law Center, *New Data Estimate 61.4 Million Women Have Coverage of Birth Control without Out-of-Pocket Costs* (Dec. 2019), https://bit.ly/3gcpmpi.

153. The Rules, the Settlement Agreement, and any other similar settlements reinstate the cost barriers to contraceptive care.

154. Additionally, the Rules, the Settlement Agreement, and any other similar settlements impose other significant informational, administrative, and logistical burdens on Plaintiffs and other women, who will need to navigate finding other sources of contraceptive care.

155. Some women will not have access to contraception at all because of the Rules, the Settlement Agreement, and any other similar settlements.

156. Congress included the Women's Health Amendment in the ACA to improve women's health by removing cost and access barriers, to protect women's economic security, and

to remedy systemic sex discrimination in the insurance market.

157. Yet by means of the Rules, the Settlement Agreement, and other similar settlements, the Departments authorize and enable employers and universities to exempt themselves from the contraceptive coverage requirement and prevent plan participants and beneficiaries from receiving the coverage through the accommodation, thus shifting to women, who are supposed to receive the coverage, the burdens and costs of supporting and underwriting their employers' and universities' religious beliefs, while at the same time directly undermining the legislative purposes of the Women's Health Amendment.

158. The Rules, the Settlement Agreement, and other similar settlements create unreasonable barriers to critical health care services for Plaintiffs and countless other women.

159. The Rules, the Settlement Agreement, and other similar settlement agreements fail to account for these important interests, are not narrowly tailored to address actual burdens on religious exercise, and lack adequate justification.

FIRST CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Settlement Agreement Violates the Administrative Procedure Act)

160. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

161. Plaintiffs are entitled to relief under the Administrative Procedure Act because the Settlement Agreement is illegal under and contrary to controlling orders and precedential decisions of the federal courts, federal statutes, and the U.S. Constitution.

162. HHS, the Department of Labor, and the Department of the Treasury are "agencies" under the Administrative Procedure Act. *See* 5 U.S.C. § 551(1).

163. The Government Defendants' decision to enter into the Settlement Agreement is a final agency action subject to judicial review under 5 U.S.C. § 551(13) and 5 U.S.C. § 704.

164. The Administrative Procedure Act requires courts to "hold unlawful and set aside" any agency action, finding, or conclusion that is "an abuse of discretion," "not in accordance with the law," or "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(A)-(C).

165. The Settlement Agreement is contrary to the Establishment Clause of the First Amendment because, among other constitutional defects, it prefers some religious beliefs and denominations over others and imposes costs, burdens, and harms on Plaintiffs to favor the religious beliefs of the University.

166. The Settlement Agreement is unlawful because it exceeds the Government Defendants' settlement authority, in contravention of law and long-standing, binding Department of Justice policy. The Government Defendants are prohibited from entering into settlement agreements that "limit[] the discretion of a[n executive] department or agency" or that would convert a federal agency's discretionary authority into a mandatory duty for the agency. *See* Memorandum from Edwin Meese III, Attorney General, to all Assistant Attorneys General and All United States Attorneys 3 (Mar. 13, 1986) (the "Meese Memo"), reprinted in U.S. Dep't of Justice, Office of Legal Pol'y, Guidelines on Constitutional Litigation 150, 152–53 (Feb. 19, 1988).

167. The Settlement Agreement is contrary to law because it violates the Women's Health Amendment, the Final Rules, and the previously operative implementing regulations (*see* 78 Fed. Reg. 39,870; 80 Fed. Reg. 41,318) by allowing group health plans and health insurance issuers to charge copayments, coinsurance, or deductibles for contraception that they otherwise cover without objection, in contravention of the statute's requirement that they "shall not impose any cost sharing requirements."

168. The Settlement Agreement is contrary to law because it violates the lawful regulations implementing the Women's Health Amendment —i.e., the regulations operative prior to the Final Rules (*see* 78 Fed. Reg. 39,870; 80 Fed. Reg. 41,318)—by allowing group health plans and health insurance issuers to refuse to comply with the accommodation process and in doing so to prevent plan participants and beneficiaries from receiving the contraceptive coverage to which they are entitled under those regulations.

169. By entering an illegal Settlement Agreement, the Government Defendants abused their discretion in violation of 5 U.S.C. § 706(2)(A).

170. Because the Government Defendants' actions are "not in accordance with law," are "in excess of authority," are "contrary to constitutional right," and are "an abuse of discretion," the Government Defendants have violated the Administrative Procedure Act.

171. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

SECOND CAUSE OF ACTION—ALL DEFENDANTS

(Settlement Agreement is Void for Illegality)

172. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

173. Under federal common law, contracts that are illegal are void *ab initio* and unenforceable. *See, e.g.*, *U.S. Nursing Corp. v. Saint Joseph Med. Ctr.*, 39 F.3d 790, 792 (7th Cir. 1994); *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 863 (N.D. Ind. 1999).

174. The Settlement Agreement is illegal under and contrary to controlling orders and precedential decisions of federal courts, federal statutes, and the U.S. Constitution.

175. The Settlement Agreement violates:

a. The Establishment Clause of the First Amendment to the U.S. Constitution.

b. Long-standing and binding Department of Justice policy that precludes Government Defendants from entering into settlement agreements that would convert a federal agency's discretionary authority into a mandatory duty for the agency.

c. The Women's Health Amendment, 42 U.S.C. § 300gg–13, to the extent that the Settlement Agreement allows group health plans and health insurance issuers to charge copayments, coinsurance, or deductibles for contraception that they otherwise are willing to cover, in contravention of the statute's requirement that they "shall not impose any cost sharing requirements."

d. Lawful regulations implementing the Women's Health Amendment, 78 Fed. Reg. 39,870; 80 Fed. Reg. 41,318.

176. The Settlement Agreement is null and void *ab initio* because it is illegal.

177. Absent declaratory and injunctive relief voiding the Settlement Agreement and enjoining its enforcement, Defendants' violations will cause ongoing harm to Plaintiffs.

THIRD CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Administrative Procedure Act—The Final Rules Violate the Substantive Requirements of the Administrative Procedure Act)

178. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

179. Plaintiffs are entitled to relief under the Administrative Procedure Act because the Rules are illegal under the Constitution and federal statutes.

180. The Administrative Procedure Act requires courts to "hold unlawful and set aside" any agency action, finding, or conclusion that is "arbitrary," "capricious," "an abuse of discretion," "not in accordance with the law," "contrary to constitutional right, power, privilege, or immunity," or "in excess of statutory . . . authority, or limitations, or short of statutory right." 5 U.S.C.

§ 706(2)(A)-(C).

181. The Rules are contrary to the Establishment Clause of the First Amendment.

182. The Rules are arbitrary, capricious, and an abuse of discretion in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), because, among other reasons, the Departments failed to:

a. offer adequate justification for the Rules;

b. tailor the Rules' exemptions to apply only when necessary to alleviate a substantial burden on religious exercise;

c. consider the Rules' deleterious effects on the health, economic security, equality, and autonomy of women and others who will lose coverage for contraception;

d. respond to significant comments regarding the Rules' detrimental effects on access to contraception, and the resulting harm to women's health, economic security, equality, and autonomy;

e. consider the weight of the hundreds of thousands of comments that were submitted for each of the previous rules relating to the contraceptive coverage requirement, or the post-promulgation comments submitted following the Interim Final Rules;

f. provide any reasoned explanation—let alone the more detailed justification that is legally required—for abandoning the Departments' earlier, detailed, and highly persuasive factual findings regarding the benefits of contraception to women's health and equality;

g. provide any reasoned explanation—let alone the more detailed justification that is legally required—for abandoning the Departments' earlier, detailed, and highly persuasive factual findings supporting their conclusion that the government has a compelling governmental interest in ensuring that individuals receive coverage of contraception without cost-sharing.

h. provide any reasoned explanation—let alone the more detailed justification that is legally required—for abandoning their own long-standing position—advanced to this Court and to multiple federal courts of appeals—that the preexisting accommodation does not substantially burden religious exercise;

i. provide any reasoned explanation—let alone the more detailed justification that is legally required—for abandoning the Departments' earlier determinations that no feasible alternatives are available and that the accommodation is the least restrictive means of furthering the government's compelling interest in the contraceptive coverage requirement;

j. consider the serious reliance interests of Plaintiffs and countless others on the contraceptive coverage requirement and preexisting accommodation process;

k. conduct an adequate regulatory-impact analysis that considers, as it must, the full scope of costs to the health, economic security, equality, and autonomy of women and others who can become pregnant.

183. The Rules are therefore arbitrary and capricious because they lack a rational connection to the problem identified, because the Departments failed to consider an important aspect of the problem, and because the agency offered an explanation for its decision that runs counter to the evidence before the agency.

184. The Rules are also arbitrary and capricious because the Departments failed to provide any reasoned explanation for their dramatic reversal of policy, let alone the more detailed justification required when, as here, there are serious reliance interests at stake and the Rules rest upon factual findings that contradict those which underlay the prior policy.

185. By issuing illegal Rules, the Government Defendants abused their discretion in violation of 5 U.S.C. § 706(2)(A).

186. Because the Government Defendants' actions are "not in accordance with law," "contrary to constitutional right," "arbitrary and capricious," and "an abuse of discretion," the Government Defendants have violated the Administrative Procedure Act.

187. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

FOURTH CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(First Amendment—Violation of the Establishment Clause)

188. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

189. Plaintiffs are entitled to relief because the Settlement Agreement and the Rules subject, and will continue to subject, Plaintiffs to deprivations of their rights under the Establishment Clause of the First Amendment to the U.S. Constitution.

190. The Establishment Clause provides that "Congress shall make no law respecting an establishment of religion."

191. The Government Defendants have violated, and will continue to violate, Plaintiffs' rights under the Establishment Clause, including in the following ways:

a. The Settlement Agreement and the Rules are governmental conduct that has and will continue to have the primary purpose and principal effect of promoting, advancing, and endorsing religion.

b. The Settlement Agreement and the Rules coercively impose religious beliefs and practices to which Plaintiffs and other affected persons do not subscribe.

c. The Settlement Agreement and the Rules excessively entangle the government with religion.

d. The Settlement Agreement and the Rules impermissibly impose on

Plaintiffs and other third parties undue costs, burdens, and harms arising from the granting of religious exemptions from the ACA, including by depriving them of, or limiting their access to, contraceptive services, a critical preventive health service, and by shifting to and imposing on them costs to obtain contraceptives and contraceptive services that they otherwise would not have to pay out-of-pocket.

e. The Settlement Agreement and the Rules impermissibly favor and prefer some denominations and religious beliefs over others.

192. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

a. Declare the Settlement Agreement between the Departments and Notre Dame void because it violates the Administrative Procedure Act, orders and precedential decisions of federal courts, and the First Amendment to the U.S. Constitution;

b. Enter a permanent injunction prohibiting Notre Dame from implementing, enforcing, or relying on the Settlement Agreement or any provision thereof;

c. Enter a permanent injunction prohibiting the Departments from implementing, enforcing, or relying on the Settlement Agreement, or any provision thereof, with respect to Notre Dame and any of the health plans that it sponsors;

d. Enjoin the Government Defendants from authorizing or permitting Notre Dame to sponsor any student or employee health plan that fails to comply with operative laws and regulations;

e. Declare that the Final Rules were issued in violation of, and violate, the

Administrative Procedure Act and the First Amendment to the U.S. Constitution;

f. Vacate and set aside the Final Rules;

g. Enter a permanent injunction prohibiting the Government Defendants from implementing or enforcing the Final Rules;

h. Retain jurisdiction until Defendants have fully satisfied their court-ordered obligations;

i. Award nominal damages in the sum of $1.00;

j. Award Plaintiffs attorneys' fees and costs, as provided by any applicable statute or regulation or the inherent powers of the Court;

k. Grant all further and additional relief that the Court may determine is just and proper.

Dated: August 20, 2020

Respectfully submitted,

_____/s/_____

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* Motion for *pro hac vice* forthcoming.

**Motion for *pro hac vice* pending.